

# Phase I/II vaccine study targeting novel HLA-A2-restricted CTL epitopes in combination with poly-ICLC in patients with recurrent malignant glioma

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## Abstract:

**Background:** We conducted a phase I/II trial to evaluate the safety and immunogenicity of a novel vaccination with  $\alpha$ -type-1-polarized dendritic cells ( $\alpha$ DC1) loaded with synthetic peptides for glioma associated antigen (GAA) epitopes and administration of poly-ICLC in HLA-A2+ patients with recurrent malignant gliomas. GAAs for these peptides are EphA2, IL-13R $\alpha$ 2, YKL-40 and gp100. **Methods:** The study enrolled twenty-two recurrent malignant glioma patients with glioblastoma (GBM) (n = 13), anaplastic astrocytoma (n = 5), anaplastic oligodendroglioma (n = 3), or anaplastic oligoastrocytoma (n = 1). Half the patients had 2nd relapse or greater. Two recurrent GBM patients had prior bevacizumab. Peptide-loaded  $\alpha$ DC1 were injected intra/periodically every two weeks for 4 injections with the possibility of boosters. 20  $\mu$ g/kg poly-ICLC was administered intramuscularly two times per week for 8 weeks. Immunogenicity was assessed by ELISPOT, tetramer, and IL-12 assays. Efficacy was determined by MRI according

to McDonald criteria. **Results:** The regimen was well-tolerated and demonstrated efficacy in heavily pre-treated patients. There were no grade 3 or greater toxicities and no dose limiting toxicities. Injection site reactions, transient fatigues and chills were the most common adverse events. Eighty-one percent (13/16) had  $\geq 1$  positive immunogenicity assay. Forty-six percent (6/13) of recurrent GBM and sixty-seven percent (6/9) of recurrent anaplastic glioma patients had tumor shrinkage or stable disease. One recurrent GBM patient sustained a complete response (CR) for greater than 14 months, and 2 patients achieved a partial response (PR). In recurrent GBM patients, the median overall survival (OS) was 12 months, 6 month OS was 80%, and 12 month OS was 46%. **Conclusions:** The novel  $\alpha$ DC1-based vaccine in combination with poly-ICLC demonstrated safety, immune-reactivity as well as efficacy in patients with recurrent malignant glioma. Given these promising results, Phase II/III clinical studies are planned in recurrent GBM. Phase I/II trials are also underway with peptide emulsion in adult low-grade and pediatric malignant glioma.